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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,629	12/01/2004	Detlef P Muller-Schulte	RO0940US(#90568)	4567

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D Peter Hochberg
D Peter Hochberg Co
1940 East 6th Street
6th Floor
Cleveland, OH 44114

EXAMINER	
JUNG, UNSU	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/516,629	MULLER-SCHULTE, DETLEF P	
	Examiner	Art Unit	
	Unsu Jung	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *1-24,43,44,46,47 and 63-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-42,45 and 48-62* is/are rejected.

7)☐ Claim(s) *25,26 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Examiner notes an error in the Office Action filed on August 23, 2005, which lists claims 25-45 and 48-62 as being in Group II. Claims 43 and 44 were inadvertently placed in Group II as the subsequent Groups III and IV include claims 43 and 44, respectively. On October 27, 2005, Examiner contacted Mr. Hochberg by telephone to inform Applicant regarding the error in Group II claims.

2. Amendments to the specification in the reply filed on December 1, 2004 have been acknowledged and entered.

3. Amendments to the claims in the reply field on December 1, 2004 have been acknowledged and entered.

4. Claims 1-65 are pending.

Election/Restrictions

5. Applicant's election with traverse of Group II (claims 25-42, 45, and 48-62) in the reply filed on September 23, 2005 is acknowledged. The traversal is on the ground(s) that each of the Groups includes a single inventive idea of the thermosensitive polymers containing at least one magnetic or metallic colloids. This is not found persuasive because the single inventive idea of thermosensitive polymers containing at least one

magnetic or metallic colloids has been shown in prior art. As stated in the Office Action filed on August 23, 2005, West et al. (WO 01/05586, Jan. 25, 2001) teaches a thermally sensitive polymer-particle composite that absorbs electromagnetic radiation and uses the absorbed energy to trigger delivery of a chemical (Abstract). Therefore, the thermosensitive polymers containing at least one magnetic or metallic colloids cannot be a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

6. The following is a quotation of the appropriate paragraphs of 37 CFR 1.69:

> (a) whenever an individual making an oath or declaration cannot understand English, the oath or declaration must be in a language that such individual can understand and shall state that such individual understands the content of any documents to which the oath or declaration relates.
>
> (b) unless the text of any oath or declaration in a language other than English is a form provided or approved by the Patent and Trademark Office, it must be accompanied by an English translation together with a statement that the translation is accurate, except that in the case of an oath or declaration filed under § 1.63, the translation may be filed in the Office no later than two months from the date applicant is notified to file the translation.

The Declaration filed December 1, 2004 fails to comply with the provisions of 37 CFR 1.69 and MPEP § 602.06 because the Oath/Declaration is in a language other than English. Oath/Declaration must be accompanied by an English translation together with a statement that the translation is accurate.

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction

of the following is required: the current specification fails to disclose a process of claim 37, which recites "the process for the production of thermosensitive polymers according to Claim 25, further comprising the step of pre-polymerizing the monomer solution for 5-120 seconds before dispersion in the organic phase."

8. The disclosure is objected to because of the following informalities: the phrase "IKA Werke" should be corrected to "IKA Works, Inc" on p22, line 16 and p23, paragraph [000090], line 13, as the company name was misspelled in the current specification.

Appropriate correction is required.

9. The use of the trademark TWEEN® (p22, line 15, p23, paragraph [000090], line 12), ULTRA-TURRAX™ (p22, line 16 and p23, paragraph [000090], line 13), INSUMAN® (p24, paragraph [000091], line 8) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

10. Claims 25 and 26 are objected to because of the following informalities: the word "a" is needed prior to the phrase "mechanical comminution." Appropriate correction is required.

11. Claim 25 is objected to because of the following informalities: the phrase "nano- or microparticles" should be corrected to "nano- or micro-particles." Appropriate correction is required.

12. Claims 26 and 32 are objected to because of the following informalities: the phrase "nano or microparticles" should be corrected to "nano- or micro-particles." Appropriate correction is required.

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 25-42, 45, 48-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claims 25 and 26 recite the limitation "the production" in line 1. There is insufficient antecedent basis for this limitation in the claim. Applicant is suggested to change "the production" to "a production."

16. Claims 25, 26, and 53 recite the limitation "the steps" in line 2. There is insufficient antecedent basis for this limitation in the claim. Applicant is suggested to change "the steps" to "steps."

17. Claims 27, 51, 54, and 60 recite the limitation "the group" in line 2. There is insufficient antecedent basis for this limitation in the claim. Applicant is suggested to change "the group" to "a group."

18. In claims 27-45 and 48-62, the term "thermosensitive polymers" in line 3 is vague and indefinite. It is unclear whether the term "thermosensitive polymers" refer to "thermosensitive polymers" of claim 25. Applicant is suggested to add "the" prior to the term "thermosensitive polymers."

19. In claims 28 and 30, the phrase "the steps" in line 3 is vague and indefinite. It is unclear whether the phrase "the steps" refer to "the steps" of claim 25. Applicant is suggested to change "the steps" to "steps."

20. In claims 28 and 49, the phrase "0.05 to 30% mol co-monomers" is vague and indefinite. It is unclear whether the phrase "0.05 to 30% by mol co-monomers" means concentration of co-monomers added or co-monomer content.

21. Claims 29, 33, 35, 40, 42, 48, and 57 recite the limitation "the group" in line 3. There is insufficient antecedent basis for this limitation in the claim. Applicant is suggested to change "the group" to "a group."

22. In claim 30, the phrase "the steps" in line 3 is vague and indefinite. It is unclear whether the phrase "the steps" refer to "the steps" of claim 25. Applicant is suggested to change "the steps" to "steps."

23. Claims 30 and 38 recite the limitation "the group" in line 4. There is insufficient antecedent basis for this limitation in the claim. Applicant is suggested to change "the group" to "a group."

24. In claim 25, the phrase "the steps" in line 5 is vague and indefinite. It is unclear whether the phrase "the steps" refer to "the steps" of claim 25. Applicant is suggested to change "the steps" to "steps."

25. In claims 35, 37, 38, 39, and 41, the phrase "the step" in line 3 is vague and indefinite. It is unclear whether the phrase "the steps" refer to "the step" of claim 25. Applicant is suggested to change "the step" to "a step."

26. Claim 45 provides for the use of thermosensitive polymers, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 45 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

27. In claims 49, 51, 56, 58, 59, and 61, the phrase "the step" in line 2 is vague and indefinite. It is unclear whether the phrase "the steps" refer to "the step" of claim 25. Applicant is suggested to change "the step" to "a step."

28. Claims 50, 58, 61, and 62 recite the limitation "the group" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Applicant is suggested to change "the group" to "a group."

Claim Rejections - 35 USC § 102

29. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

30. Claims 25, 26, 28-31, 35-38, 45, 49-52, and 56-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Müller-Schulte (U.S. Patent No. 6,204,033, Mar. 20, 2001).

Müller-Schulte anticipates instant claims by teaching a process for a production of thermosensitive polymers comprising steps of dispersing at least one of magnetic or metallic colloids in an aqueous monomer solution, suspending the aqueous monomer solution through mechanical comminution in an organic phase that is not miscible with water after addition a multifunctional cross-linking agent and a radical initiator and radically polymerizing the organic phase to nano- or micro-particles (Abstract).

With respect to claims 28, 29, 49, and 50, Müller-Schulte teaches the process of claim 25, further comprising the step of adding 0.05 to 30% by mol co-monomers to the monomer solution, wherein the co-monomers are acrylic acid (column 15, lines 39-42).

With respect to claims 30, 31, 51, and 52, Müller-Schulte teaches the process of claim 25, further comprising a step of adding a magnetic particle size of 10-200 nm in magnetic colloid form (column 5, lines 38-42).

With respect to claims 35, 36, 56, and 57, Müller-Schulte teaches the process of claim 25, further comprising the step of adding at least one surfactive substance such as polyoxyethylene sorbitan fatty acid esters (column 4, lines 23-28) to the organic phase at 0.05 to 15% by weight (column 4, lines 51-56).

With respect to claim 37, Müller-Schulte teaches the process of claim 25, further comprising a step of pre-polymerizing the monomer solution for one minute before dispersion in the organic phase (column 9, lines 23-33).

With respect to claims 38 and 58, Müller-Schulte teaches the process of claim 25, further comprising a step of bonding a compound from a group consisting of antibodies, peptides, proteins, enzymes, streptavidin, oligonucleotides, oligosaccharides, and DNA (Abstract).

With respect to claim 45, Müller-Schulte teaches the use of thermosensitive polymers containing at least one of magnetic or metallic colloids produced by the process of claim 25 as carriers for active agents in medical therapy and diagnostics (column 8, lines 64-67), separation media in column chromatography (column 7, line 56-column 8, line 17), and separation media for cells, DNA, and proteins (column 9, lines 1-17).

31. Claims 34 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Müller-Schulte (U.S. Patent No. 6,204,033, Mar. 20, 2001) in light of Shishikura et al. (U.S. Patent No. 5,990,262, Nov. 23, 1999).

Müller-Schulte teaches a process for a production of thermosensitive polymers as discussed above. Müller-Schulte further teaches that organic solvents such as hexane, heptane, cyclohexane, or petroleum ether are used in the process for the production of the thermosensitive polymers (column 7, lines 45-51). However, Müller-Schulte fails to specifically disclose that these organic phase solvents have a polar solubility parameter of 5-10 $(cal/cm^3)^{1/2}$.

Shishikura et al. teaches that heptane has a solubility parameter of 7.4 $(cal/cm^3)^{1/2}$. Therefore, one of ordinary skill in the art would recognize that the organic solvent of Müller-Schulte would inherently have solubility parameter of 7.4 $(cal/cm^3)^{1/2}$.

Claim Rejections - 35 USC § 103

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

33. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

34. Claims 27, 32, 33, 48, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Müller-Schulte (U.S. Patent No. 6,204,033, Mar. 20, 2001) in view of Elaissari et al. (U.S. Patent No. 6,133,047, Published Dec. 4, 1997).

Müller-Schulte teaches a process for a production of thermosensitive polymers as discussed above. However, Müller-Schulte fails to teach a process for a production of thermosensitive polymers, wherein the aqueous monomer solution comprises at least one monomer selected from a group consisting of N-isopropylacrylamide (NIPAM), N-substituted acrylamides, and N-substituted methacrylamides.

Elaissari et al. teaches a method of producing superparamagnetic monodispersed particles comprising a core of a first polymer, an internal layer of a second polymer coating the core and an external layer of a third polymer coating the magnetic layer and capable of interacting with at least one biological molecule (Abstract). These particles may be used to isolate at least one biological molecule from a liquid specimen (Abstract). The method of Elaissari et al. makes it possible to achieve high contents of incorporated magnetic filler since the process employed makes it possible to distribute the magnetic filler in the form of multilayers (column 1, lines 37-40). This results in a considerable advantage, namely the possibility of effective separation of the particle s of Elaissari et al. from the specimen, without having recourse to the combined action of another technique (column 1, lines 40-44). The first polymer consists of polystyrene and the second polymer comprises a heat-sensitive polymer such as NIPAM (column 1, line 56-column 2, line 4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the process of Müller-Schulte with a use of encapsulated magnetic colloids having a polymer core consisting of polystyrene and a well known heat-sensitive polymer such as NIPAM as taught by Elaissari et al. in order to generate thermosensitive polymeric particles, which may be used to isolate at least one biological molecule from a liquid specimen.

35. Claims 39-41 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Müller-Schulte (U.S. Patent No. 6,204,033, Mar. 20, 2001) in view of Havas et al. (U.S. Patent No. 4,375,399, Mar. 1, 1983).

Müller-Schulte teaches a process for a production of thermosensitive polymers as discussed above. However, Müller-Schulte fails to teach a process for a production of thermosensitive polymers, further comprising a step of encapsulating active agents in the polymers by adding the active agents to a monomer solution containing at least one of magnetic or metallic colloids.

The methods of encapsulating proteins and enzymes in polymers as those disclosed in Havas et al. are well known in the art. Havas et al. teaches a method of mixing polymers such as polyvinyl alcohol with a protein or enzyme to form an active cross-linked net (column 3, lines 52-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Müller-Schulte with a method of mixing polymers such as polyvinyl alcohols with active agents such as proteins or enzymes as

taught by Havas et al. in order to incorporate active agents in thermosensitive polymers at the time of polymerization.

With respect to claims 41 and 61, Havas et al. teaches a method of mixing polyvinyl alcohols to the active agents in an amount of 10% by weight (column 4, line 54).

36. Claims 42 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Müller-Schulte (U.S. Patent No. 6,204,033, Mar. 20, 2001) in view of Havas et al. (U.S. Patent No. 4,375,399, Mar. 1, 1983) as applied to claims 39-41 and 59-61 above, and further in view of Andrianov et al. (U.S. Patent No. 5,529,777, June 25, 1996).

Andrianov et al. teaches a method of encapsulating an antigen, wherein the antigen is mixed with a polymer solution, microparticles are rapidly formed of the polymer and antigen to form a stable biodegradable microparticle (column 5, lines 23-28), which can be used as an immunogenic vaccine composition (column 15, lines 3-10). Andrianov et al. further teaches that polymers comprising carbohydrates, which includes glucose, are used in the method of encapsulating an antigen (column 9, lines 1-11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Müller-Schulte in view of Havas et al. with a method of using biodegradable polymers such as glucose as taught by Andrianov et al. in order to encapsulate an active agent in polymers for use in therapeutic settings, where biodegradable polymers are desirable.

Double Patenting

37. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

38. Claims 25, 26, 28, 30-33, 35, 49, 51-54, and 56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, and 14 of U.S. Patent No. 6,204,033. Although the conflicting claims are not identical, they are not patentably distinct from each other because each teaches a process for a production of thermosensitive polymers comprising steps of dispersing at least one of magnetic or metallic colloids in an aqueous monomer solution, suspending the aqueous monomer solution through mechanical comminution in an organic phase that is not miscible with water after addition a multifunctional cross-linking agent and a radical initiator and radically polymerizing the organic phase to nano- or micro-particles and it would be obvious to one of ordinary skill in the art that the more narrow claims of the U.S. Patent No. 6,204,033 would encompass the claims of the current application.

Conclusion

39. No claim is allowed.

40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Unsu Jung, Ph.D.
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
8/14/05